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LANDO & ANASTASI, LLP
ONE MAIN STREET, SUITE 1100
CAMBRIDGE, MA 02142

EXAMINER	
MCKANE, ELIZABETH L	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/770,241
Filing Date: February 02, 2004
Appellant(s): LAUGHARN ET AL.

Elias Domingo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12 January 2009 appealing from the Office action mailed 27 September 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

It is further noted that the Amendment After Final filed 10 January 2008 overcomes the rejection of claims 7 and 36 under 35 U.S.C. §112 and the objection to claims 32 and 33. Therefore, the rejection under 35 U.S.C. §112 and the claim objection have been withdrawn.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 10 January 2008 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner: The rejection of claims 7 and 36 and 35 U.S.C. §112. Furthermore, the objection to claims 32 and 33, a non-appealable issue, has also been withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

HASHIZUME, Chieko et al. "Kinetic Analysis of Yeast Inactivation by High Pressure Treatment at Low Temperatures," Biosci. Biotech. Biochem., vol.59, no.8 (1995), pp. 1455-1548.

HAYAKAWA, I. et al. "Oscillatory Compared with Continuous High Pressure Sterilization on *Bacillus stearothermophilus* Spores," Journal of Food Science, vol.59, no.1 (1994), pp.164-167.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, 7, 9-14, and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashizume et al. ("Kinetic Analysis of Yeast Inactivation by High Pressure Treatment at Low Temperatures") in view of Hayakawa et al. ("Oscillatory Compared with Continuous High Pressure Sterilization on *Bacillus stearothermophilus* Spores").

With respect to claims 1, 2, 6, 7, 13, 32, 33, 35, and 37, Hashizume et al. teaches a method for sterilizing a foodstuff material (which would necessarily contain desired biomolecules such as nutrients, proteins, carbohydrates, etc.) wherein the material is provided at ambient temperature and pressure (i.e. 1 atm), exposed to an elevated pressure between 120 and 300 MPA (17,400 to 43,500 psi), and the pressure released (e.g. decreased). In short, the material being sterilized undergoes a single pressurization cycle. The material is preferably at a temperature of -20° to 50°C during pressurization. See page 1455. Moreover, the Temperature-Pressure Diagram in Figure 4 of Hashizume et al. illustrates that pressure inactivation improves as the temperature either drops below –20 ºC or rises above 40 ºC. Both temperatures are

"below 45 ºC", as claimed. As previously stated, Hashizume et al. discloses a continuous application of high pressure upon the sample and does not disclose repeatedly cycling the pressure. However, this concept is evidenced by Hayakawa et al., which reference discloses that oscillatory (cyclic) pressurization is more effective than continuous pressurization in sterilizing resistant microorganisms (spores). See Abstract; page 165, "Oscillatory pressurization". Since Hashizume et al. envisions use of the high pressure treatment on all types of microorganisms, not just yeasts, it would have been obvious to use the cyclic pressurization of Hayakawa et al. in the method of Hashizume et al., in order to destroy resistant microorganisms as well.

As to claim 9, it would have been obvious to optimize the number of pressurization cycles, as such is readily determinable through routine experimentation.

With respect to claim 10, the decreased pressure of Hashizume et al. (1 atm or 14.7 psi) "is half of the elevated pressure or less." Nevertheless, it is deemed obvious to one of ordinary skill in the art to optimize the pressure differential for the particular treatment parameters through routine experimentation.

As to claims 11 and 12, since Hashizume et al. discloses treating the material at a temperature from –20 º to 50 ºC, it would have been obvious to bring it to this temperature from ambient by either cooling or warming. Similarly, it would have been obvious to bring the material back to ambient temperature after treatment by either cooling or warming, dependent upon the treatment temperature.

With respect to claim 14, the material of Hashizume et al. is initially contaminated with yeast (fungus).

As to claim 34, Hashizume et al. teaches that inactivation or microorganisms and the "[r]etention of fresh flavor is the advantage of high pressure treatment". See page 1457. As the retention of fresh flavor is related to the preservation of macromolecules such as proteins, carbohydrates, and nutrients, the pressure treatment of the prior art is capable of maintaining the biological activity of the desired macromolecules.

With respect to claim 36, it is deemed obvious to one of ordinary skill in the art to apply the method of Hashizume et al. with Hayakawa et al. to the sterilization of all types of microorganisms as one would have had an expectation of success when doing so since Hashizume et al. envisions use of the high pressure treatment on all types of microorganisms, not just yeasts.

(10) Response to Argument

A. Claims 1, 2, 6, 7, 9-14, and 32-37 would not have been obvious over the disclosure of Hashizume in view of the disclosure of Hayakawa.

Appellant argues on page 12 of the Brief that "one would not arrive at methods for sterilizing material at temperatures below 45 °C using cycled pressure. Instead, one would be motivated to use the methods clearly taught by Hayakawa" – that is, one would have been motivated to use the higher temperatures taught by Hayakawa et al.. The Examiner respectfully disagrees.

In fact, Hashizume et al. discloses the known use of pressure treatment at high temperatures (i.e. above 60 °C) for successful destruction of spores. Yet Hashizume et al. further teaches that the known use of high temperatures is *undesirable* due to "deterioration of the fresh taste and flavor" (page 1455, second full paragraph). Thus, Hashizume et al. introduces the use of high pressure sterilization *at low temperatures*. Therefore, one of ordinary skill in the art would not be motivated to use the higher temperatures taught by Hayakawa et al., as alleged by Appellant, since doing so would cause deterioration of fresh taste and flavor.

Appellant further submits that as Hashizume et al. teaches that "[n]o or little inactivation was observed for the pressurization below 180 MPa at temperatures between 0 °C and 40 °C," there would be no expectation of success using lower temperatures. However, Hashizume et al. further states that "a rapid inactivation" took place at 180 MPa when the temperature was below -10 °C. Further, Figure 2A evidences that inactivation is considerable between 40 °C and 45 °C. The instant claims require only a temperature "below 45 °C" and both -10 °C and 40 °C are certainly "below 45 °C".

Nevertheless, the secondary reference to Hayakawa et al. discloses that regardless of pressure and temperature, the cyclic exposure to pressure improves microorganism activation. In fact, Hayakawa et al. teaches that cyclic (oscillatory pressurization) enables one to decrease the pressure applied at a given temperature. See page 165, "Oscillatory pressurization." This would have motivated one of ordinary

skill in the art to apply the concept of oscillatory pressurization to the method of Hashizume et al..

B. Claims 7 and 36 are not indefinite under 35 U.S.C. 112, second paragraph.

The Amendment After Final filed 10 January 2008 and entered overcomes the rejection of claims 7 and 36 under 35 U.S.C. §112, second paragraph. Therefore, this rejection has been withdrawn.

C. Claims 32 and 33 should not be objected to due to a misspelling of the word "macromolecule.

The Amendment After Final filed 10 January 2008 and entered overcomes the objection to claims 32 and 33. The objection, a non-appealable issue, has therefore been withdrawn.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

Conferees:

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/PATRICK RYAN/
Supervisory Patent Examiner, Art Unit 1795